

Serial No.: 10/816,680  
Docket No.: ECV-5587CON  
Amendment dated May 9, 2005  
Responsive to Office Action of November 15, 2004

### REMARKS

Claims 1-47 are pending in the application. The Examiner rejected the claims under 35 U.S.C. § 112. Reconsideration of the application in view of the following remarks is respectfully requested.

### CLAIM REJECTIONS UNDER 35 U.S.C. § 112

#### The rejection under 35 USC § 112, first paragraph

The Examiner rejected claims 1-47 under 35 U.S.C. § 112, first paragraph on the basis that they fail "to comply with the enablement requirement." Applicants submit that this rejection is improper.

The Examiner acknowledges that applicants obtained promising results during the experimental phase of the application. However, the Examiner questions whether the applicants have "sufficiently enabled the claimed treatment when most of the "treated" population dies." The Examiner asserts that 2/3 of the dogs used in the treatment protocol died.

Applicants respectfully submit that the Examiner is incorrect in assuming that 2/3 of the dogs died in the treatment protocol. A total of 12 dogs were used in the animal studies. Out of the 12 dogs, 2 died. Thus, it is not correct to state that 2/3 of the dogs died. 2/3 of the dogs in the fibrin + delayed release Paclitaxel experiments died but none of the dogs in the fibrin + micellar Paclitaxel experiments died. See Table 2. Therefore, only 2/6 of the dogs died in the fibrin + Paclitaxel experiments.

More importantly, though, even the 2 dogs that died in the the fibrin + delayed release Paclitaxel experiments did not die on account of the drug combination. One animal died due to uncontrolled bleeding and the other animal was euthanized because it had an altered mental state and a large swelling of the left carotid area. However, the death of neither animal was ascribed to the drug combination.

For the foregoing reasons, the Examiner's enablement argument appears to be factually flawed. Therefore, because the Examiner has not provided a sound basis for questioning the applicant's enablement, applicants submit that the specification teaches the manner and process of making and using the invention in terms which correspond in scope to the claims.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

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The rejection under 35 USC § 112, second paragraph

The Examiner rejected claims 5, 24, 31, 33, 42, and 44 under 35. U.S.C. § 112, second paragraph as being indefinite. The Examiner correctly notes that two members of the claimed Markush group are "synthetic polymers" and "synthetically modified polymers." The Examiner appears to believe that the two terms connote the same substance unless the latter term is modified to become "synthetically modified natural polymers."

Applicants respectfully disagree that the two Markush members are the same. One connotes a synthetic polymer, e.g., polyethylene glycol. The other connotes a polymer, which can be natural or synthetic, that has been modified synthetically. For example, certain drug moieties may be added to synthetic PEG to make a synthetically modified polymer. Therefore, the term "synthetically modified polymers" must be construed to include both synthetic and natural polymers that have been synthetically modified. For the foregoing reasons, the Examiner is respectfully requested to withdraw this rejection.

**DOUBLE PATENTING REJECTION**

The Examiner rejected claims 1-47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-66 of U.S. Patent No. 6,730,313. Without agreeing with the propriety of the rejection, Applicants hereby submit, without prejudice, a Terminal Disclaimer disclaiming the term of any patent granted on the present application beyond the expiration date of the aforementioned patent. Filing of the Terminal Disclaimer should suffice to overcome the double patenting rejection and, therefore, applicants respectfully request withdrawal of this rejection.

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### PETITION FOR EXTENSION OF TIME TO RESPOND

Pursuant to 37 C.F.R. 1.136(a), Applicants hereby request an extension of time for **Three Months** to respond to the above-referenced Office Action. The Commissioner is hereby authorized to charge the required fee of \$1,020.00 to Deposit Account No. 50-1225 (Docket No. ECV-5587CON). A duplicate copy of this sheet is enclosed.

### CONCLUSION


Accordingly, in view of the above amendments and remarks, it is submitted that this application is now ready for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (949) 250-6801.

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225.

Dated: May 9, 2005

Respectfully submitted,

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